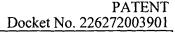


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		Application Number	10/615,119				
TRANSMITT	AL	Filing Date	July 7, 2003				
FORM		First Named Inventor	Carmel M. LYNCH				
(to be used for all correspondence after	rinitial filing)	Art Unit	Not Yet Assigned				
,	3,	Examiner Name	Not Yet Assigned				
Total Number of Pages in This Submiss	sion 10	Attorney Docket Number	226272003901				
	ENCLOS	URES (check all th	nat apply)				
Fee Transmittal Form Drawing(s)			After Allowance Communication to Group  Appeal Communication to Board of				
Fee Attached	Licensing-rel	ated Papers	Appeals and Interferences				
Amendment/Reply	Petition		Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)				
After Final	Petition to Co	onvert to a Provisional	Proprietary Information				
Affidavits/declaration(s)	Power of Attorney, Revocation Change of Correspondence Address		Status Letter				
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Express Abandonment Request			Form PTO-1449 (6 pages)     Return postcard				
x Information Disclosure Statement (3 pages)	CD, Number	of CD(s)	2. Wording postedia				
Certified Copy of Priority Document(s)							
Response to Missing Parts/ Incomplete Application	Remarks						
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under 37 CFR 1.52 or 1.53							
SIGNA	TURE OF APPLICA	ANT, ATTORNEY, OR AG	ENT				
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Laura Spires

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Carmel M. LYNCH et al.

Serial No.:

10/615,119

Filing Date:

July 7, 2003

For:

AMPLIFIABLE ADENO-ASSOCIATED

VIRUS (AAV) PACKAGING

CASSETTES FOR THE PRODUCTION OF RECOMBINANT AAV VECTORS

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

# INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related application Serial Number 09/180,114, filed October 20, 1998, and, accordingly, copies are not included herewith. This protocol conforms with 37 C.F.R.

§1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make these documents of record in the application.

	This In	formation Disclosure Statement is submitted:						
	With	the application; accordingly, no fee or separate requirements are required.						
	Befor	re the mailing of a first Office Action after the filing of a Request for Continued						
	Examination under § 1.114.							
$\boxtimes$	With	Within three months of the application filing date or before mailing of a first Office						
	Actio	n on the merits; accordingly, no fee or separate requirements are required.						
	After	receipt of a first Office Action on the merits but before mailing of a final Office						
	Actio	n or Notice of Allowance.						
		A fee is required. A check in the amount of is enclosed.						
		A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached						
		to this submission in duplicate.						
		A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee						
		is believed to be due.						
	After	mailing of a final Office Action or Notice of Allowance, but before payment of the						
	issue	fee.						
		A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the						
		amount of is enclosed.						
		A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal						
		form (PTO/SB/17 is attached to this submission in duplicate.)						

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does

not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 226272003901. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: September 23, 2003

Respectfully submitted,

Catherine M. Polizzi Registration No. 40,130

Morrison & Foerster LLP 755 Page Mill Road

Palo Alto, California 94304-1018

Telephone: (650) 813-5651 Facsimile: (650) 494-0792

Form PTO-1449	Docket Number 226272003901 Application Number 10/615,		
O INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant  Carmel M. LYNCH et al.		
(Use several sheets if necessary)	Filing Date July 7, 2003	Group Art Unit Not Yet Assigned	

## **U.S. PATENT DOCUMENTS**

Mailing Date September 3 2003

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	12/22/1992	5,173,414	Lebkowki et al.			
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Examiner Initials	Ref. No.	Date	Document No.		Country	Class	Subclass	Transl YES	lation NO
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	10.	05/29/1992	WO 92/08796	WIPO					
	11.	06/23/1994	WO 94/13788	WIPO					
	12.	12/08/1994	WO 94/28143	WIPO					
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	22.	09/12/1997	WO 97/32990	WIPO					
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	23.	06/25/1998	WO 98/27204	WI	PO				
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	25.		et al., (May 1996) "I irol. 70(5):3235-324		vo model of adeno-as	sociated vi	rus vector per	sistence a	nd
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	Sheet 3 of 6
Docket Number 226272003901	Application Number 10/615,119
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Carme	el M. LYNCH et al.
Filing Date July 7, 2003	Group Art Unit Not Yet Assigned
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PTO/SB/08 (2-92) Sheet 4 of 6 Application Number 10/615,119 Docket Number 226272003901 MATION DISCLOSURE CITATION Applicant Carmel M. LYNCH et al. IN AN APPLICATION Filing Date July 7, 2003 Group Art Unit Not Yet Assigned (Use several sheets if necessary) Mailing Date September 3, 2003 Hölscher, C. et al., (1994) "Cell lines inducibly expressing the adeno-associated virus (AAV) rep 55. gene: Requirements for productive replication of rep-negative AAV mutants" J. Virol. 68(11):7169-7177. Hölscher, C. et al., (November 1995) "High-level expression of adeno-associated virus (AAV) rep78 56. or rep68 protein is sufficient for infectious-particle formation by a rep-negative AAV mutant" J. Virol. 69(11):6880-6885. Kaplitt, M.G. et al., (October 1994) "Long-term gene expression and phenotypic correction using 57. adeno-associated virus vectors in the mammalian brain" Nature Genetics 8:148-154. Kelman, Z. and O'Donnell, M. (1994) "DNA replication: Enzymology and mechanisms" Curr. Opin. 58. Genet. Dev. 4:185-195. Khleif, S.N. et al., (1991) "Inhibition of cellular transformation by the adeno-associated virus rep 59. gene" Virology 181:738-741. Kornberg, A. and Baker, T.A. (1992) DNA Replication, Second Edition, Freeman, W.H. & Co., New 60. York, Table of Contents: v-ix. Kotin, R.M. et al., (December 1992) "Characterization of a preferred site on human chromosone 19q 61. for integration of adeno-associated virus DNA by non-homologous recombination" The EMBO J. 11(13):5071-5078. Labow, M.A. et al., (April 1987) "Adeno-associated virus gene expression inhibits cellular 62. transformation by heterologous genes" Mol. Cell. Biol. 7(4):1320-1325. Laface, D. et al. (February 1988) "Gene transfer into hematopoietic progenitor cells mediated by an 63. adeno-associated virus vector" Virology 162(2):483-486. Laughlin, C.A. et al., (November 1979) "Spliced adenovirus-associated virus RNA" Proc. Natl. 64. Acad. Sci. USA Biochemistry 76(11):5567-5571. Laughlin, C.A. et al., (1983) "Cloning of infectious adeno-associated virus genomes in bacterial 65. plasmids" Gene 23:65-73. Lebkowski, J.S. et al., (October 1988) "Adeno-associated virus: A vector system for efficient 66. introduction and integration of DNA into a variety of mammalian cell types" Mol. Cell. Biol. 8(10):3988-3996. Linden, R.M. et al., (October 1996) "Site-specific integration by adeno-associated virus" Proc. Natl. 67. Acad. Sci. USA Colloquium Paper 93:11288-11294. Lupton, S.D. et al., (June 1991) "Dominant positive and negative selection using a hygromycin 68. phosphotransferase-thymidine kinase fusion gene" Molecular and Cellular Biology 11(6):3374-3378. Lynch, C.M. et al., (April 1997) "Adeno-associated virus vectors for vascular gene delivery" Circ. 69. Res. 80(4):497-505. McLaughlin, S.K. et al., (June 1988) "Adeno-associated virus general transduction vectors: Analysis 70. of proviral structures" J. Virol. 62(6):1963-1973.

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PTO/SB/08 (2-92) Sheet 5 of 6 Application Number 10/615,119 Docket Number 226272003901 AFORMATION DISCLOSURE CITATION Applicant Carmel M. LYNCH et al. IN AN APPLICATION (Use several sheets if necessary) Filing Date July 7, 2003 Group Art Unit Not Yet Assigned Mailing Date September 23 2003 Mendelson, E. et al., (1988) "Expression and rescue of a nonselected marker from an integrated AAV 71. vector" Virology 166:154-165. Miller, J.H. and Calos, M.P. eds., (1987) Current Communications in Molecular Biology, Gene 72. transfer vectors for mammalian cells, Cold Spring Harbor Laboratory, Table of Contents: vii-ix. Muro-Cacho, C.A. et al., (1992) "Gene transfer in human lymphocytes using a vector based on adeno-73. associated virus" J. Immunotherapy 11(4):231-237. Muzyczka, N. (1992) "Use of adeno-associated virus as a general transduction vector for mammalian 74. cells" Current Topics in Microbiol. and Immunol. 158:97-129. Rich, D.P. et al., (July 12, 1991) "Effect of deleting the R domain on CFTR-generated chloride 75. channels" Science 253:205.207 Rose, J.A. (1974) "Chapter 1: Parvovirus reproduction" Comprehensive Virology 3:1-61. 76. Sambrook, J. et al., (1989) Molecular cloning: a laboratory manual, 2nd edition, Cold Spring Harbor 77. Laboratory Press, Table of Contents: xi-xxxviii. Samulski, R.J. et al., (September 1989) "Helper-free stocks of recombinant adeno-associated viruses: 78. Normal integration does not require viral gene expression" J. Virol. 63(9):3822-3828. Samulski, R.J. et al., (March 1982) "Cloning of adeno-associated virus into pBR322: Rescue of intact 79. virus from the recombinant plasmid in human cells" Proc. Natl. Sci. USA Microbiology 79:2077-2081. Samulski, R.J. et al., (October 1987) "A recombinant plasmid from which an infectious adeno-80. associated virus genome can be excised in vitro and its use to study viral replication" J. Virol. 61(10):3096-3101. Senapathy, P. and Carter, B.J. (April 10, 1984) "Molecular cloning of adeno-associated virus variant 81. genomes and generation of infectious virus by recombination in mammalian cells" J. Biol. Chem. 259(7):4661-4666. Sheppard, D.N. et al., (March 25, 1994) "The amino-terminal portion of CFTR forms a regulated CI 82. channel" Cell 76:7091-1098. Simonsen, C.C. et al., (May 1983) "Isolation and expression of an altered mouse dihydrofolate 83. reductase cDNA" Proc. Natl. Acad. Sci. USA Biochemistry 80:2495-2499. Srivastava, A. et al., (February 1983) "Nucleotide sequence and organization of the adeno-associated 84. virus 2 genome" J. Virol. 45(2):555-564. Srivastiva, C.H. et al., (October 1989) "Construction of a recombinant human parvovirus B 19: 85. Adeno-associated virus 2 (AAV) DNA inverted terminal repeats are functional in an AAV-B 19 hybrid virus" Proc. Natl. Acad. Sci. USA, Medical Sciences 86:8078-8082. DATE CONSIDERED: **EXAMINER:** 

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in

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PTO/SB/08 (2-92) Sheet 6 of 6

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